FDA 510(k) Premarket Notification

CLEARED

K241081 3D OPTICAL COHERENCE TOMOGRAPHY 3D OCT-1 (type: Maestro2)

Jul 17, 2024
89 days to decision

K241081 · Product code: **OBO** · Ophthalmic
Source: https://www.510kdatabase.net/k241081/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tomography, Optical Coherence (OBO)
Date received	Apr 19, 2024
Decision date	Jul 17, 2024
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	IMAGEnet6 Ophthalmic Data System

APPLICANT

Company	**Topcon Corporation**
Location	North Reading, MA, US
Contact	Kitawaki Ryota
Website	http://www.topcon.com
510(k) history	13 submissions · 13 cleared · 2014-2025

REGULATORY CONSULTANT

Consulting firm	**Orasi Consulting**
Contact	Lena Sattler

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

CLINICAL EVIDENCE - NCT04701931

OCT Angiography Software Evaluation Study

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	135 patients (actual)
Study sites	2 sites
Condition studied	Retina Condition Followed by Fluorescein Angiography Imaging
Study type	Observational
Completion date	Jun 6, 2023
Sponsor	Topcon Corporation (Industry)

Primary outcome

OCTA image quality

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04701931